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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/524,626	02/10/2005	Peter Aadal Nielsen	06275-438US1/100655-1P US	8723

26164 7590 12/27/2006

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EXAMINER	
RAHMANI, NILOOFAR	
ART UNIT	**PAPER NUMBER**
1625	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/27/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/524,626	NIELSEN ET AL.	
	Examiner	Art Unit	
	Niloofar Rahmani	1625	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 February 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-4,6,7 and 9-11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4,6,7 and 9-11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Claims 1-4, 6-7, and 9-11 are pending and claims 5, 8 are cancelled.

2. ***Priority***

This application is filed on 02/10/2005, which is a 371 of PCT/SE03/01272, filed on 08/13/2003, which claims the priority of SWEDEN 0202463, filed on 08/14/2002.

3. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 6 is rejected because the claims are self-conflicting. Pharmaceutical composition by definition must be effective yet non-toxic. Claim 6 is pharmaceutical composition without dosage limitation i.e. included both ineffective and toxic amount. It is recommended that "therapeutically effective amount" be incorporated in the claims.

4. ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 7 and 9-10 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

There are many factors to be considered when determining whether there is sufficient evidence to support a determination that a disclosure does not satisfy the enablement requirement and whether any necessary experimentation is "undue". These factors include 1) the breadth of the claims, 2) the nature of the invention, 3) the state of the prior art, 4) the level of one of ordinary skill, 5) the level of predictability in the art, 6) the amount of direction provided by the inventor, 7) the existence of working examples, and 8) the quantity of experimentation needed to make or use the invention based on the content of the disclosure. In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1404 (Fed. Cir. 1988).

1) The breadth of the claims.
2) The nature of the invention,
3) The state of the prior art,
4) The level of one of ordinary skill,
5) The level of predictability in the art,
6) The amount of direction provided by the inventor,
7) The existence of working examples,
8) The quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The nature of the invention: The instant invention is drawn to the method of treating or reducing the risk of, a human disease or condition in which inhibition

of ItK kinase activity is beneficial, wherein the diseases are asthma or allergic rhinitis.

The state of the prior art: "The survival and apoptosis of eosinophils is of pivotal importance for controlling allergic diseases such as asthma and rhinitis. The treatment with dibutyryl cyclic AMP (dbcAMP) increased eosinophil survival with a concomitant decrease of apoptosis in a dose-dependent manner. The pretreatment with a protein kinase A (PKA) inhibitor blocked the effects of dbcAMP on survival and apoptosis of eosinophils. When eosinophils were treated with pharmacological inhibitors of protein kinases prior to exposure to dbcAMP or IL-5, only the mitogen-activating protein kinase (MAPK) inhibitor, PD098059, was partly able to block dbcAMP-induced augmentation of eosinophil vialility." (Chang et al., Celular Immunology, Vol. 203, 2000, pages 29-38.

The predictability in the art: It is noted that the pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. *In re Fisher*, 427 F. 2d 833, 166 USPQ 18 (CCPA 1970) indicates that the more unpredictable an area is, the more specific enablement is necessary in order to satisfy the statute. In the instant case, the instantly claimed invention is highly unpredictable since one skilled in the art would recognize that in regards to the therapeutic effects, whether or not the compounds of formula (I) would be useful for treating or reducing the risk of, a human disease or condition in which inhibition of ItK kinase activity is beneficial, wherein the diseases are asthma or allergic rhinitis.

Amount of guidance/working examples: However, on page 61-62 applicants have provided some examples of inhibition of Kinase ItK using the compounds of formula (I). Applicant has not guidance or examples for treating diseases such as asthma or allergic rhinitis. The specification does not seem to enable the correlation between a compound of formula (I) and the treating diseases such as asthma or allergic rhinitis.

The breadth of the claims: The breadth of claims is drawn to method of treating or reducing the risk of, a human disease or condition in which inhibition of ItK kinase activity is beneficial, wherein the diseases are asthma or allergic rhinitis.

The quantity of undue experimentation needed: Since the guidance and teaching provided by the specification is insufficient for treating or reducing the risk of, a human disease or condition in which inhibition of ItK kinase activity is beneficial, wherein the diseases are asthma or allergic rhinitis, one of ordinary skill in the art, even with high level of skill, is unable to use the instant compounds as claimed without undue experimentation.

The level of the skill in the art: The level of skill in the art is high. However, due to the unpredictability in the pharmaceutical art, it is noted that each embodiment of the invention is required to be individually assessed for physiological activity by in vitro and in vivo screening to determine which compounds exhibit the desired pharmacological activity and which diseases would benefit from this activity.

Taking all of the above into consideration, it is not seen where the instant claims 7 and 9-10, for method of treating or reducing the risk of, a human disease or condition in which inhibition of ItK kinase activity is beneficial, wherein the diseases are asthma or allergic rhinitis, have been enabled by the instant specification.

5. *Claim Rejections - Obvious Double Patenting*

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 168 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130 (b).

Effective January 1,1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-7, and 9-11 are rejected under the judicially created doctrine obviousness-type double patenting as being unpatentable over the claims 1-4, 6-7, 9-11 of US 2005/0215582. Although the conflicting claims are not identical, they are not patentably distinct from each other because the current invention embraces the invention claimed in the above patent.

Determination of the scope and content of the prior art (MPEP §2141.01)

Nielsen et al. of US 2005/0215582 claimed identical compounds in claims 1-4, 6-7, and 9-11 as the instant claims 1-4, 6-7, and 9-11.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the instant claims and the issued claims is the claims are not word for word identical but the scope of both sets of claims overlaps mostly significantly with each other.

Finding of prima facia obviousness-rational and motivation (MPEP §2142.2143)

The instant claims 1-4, 6-7, and 9-11 are therefore fully embraced by the issued claims 1-4, 6-7, and 9-11 of US 2005/0215582.

6. *Claim Rejections - 35 USC § 102*

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

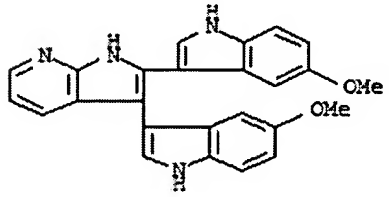
(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined

under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1, 3-4, 6-7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Cox et al. US 2004/0053931. Cox et al. disclosed the instant claimed compound

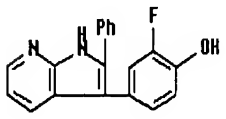
CN 1H-Pyrrolo[2,3-b]pyridine, 2,3-bis(5-methoxy-1H-indol-3-yl)-



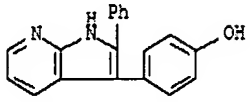
and pharmaceutical composition , in particular the ability to inhibit kinases. Therefore, the instant claims are anticipated by Cox et al.

7. Claims 1, 3-4, 6-7, and 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Kato et al. JP 2001122855. Kato et al. disclosed the instant claimed compounds

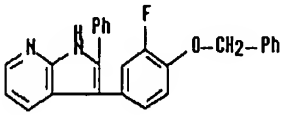
CN Phenol, 2-fluoro-4-(2-phenyl-1H-pyrrolo[2,3-b]pyridin-3-yl)-



CN Phenol, 2-fluoro-4-(7-oxido-2-phenyl-1H-pyrrolo[2,3-b]pyridin-3-yl)-



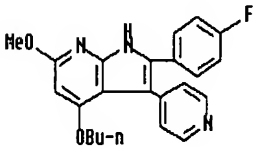
CN 1H-Pyrrolo[2,3-b]pyridine, 3-[3-fluoro-4-(phenylmethoxy)phenyl]-2-phenyl-



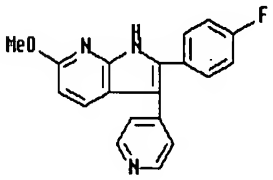
and pharmaceutical compositions having activation effect for estrogen receptor-β. Therefore, the instant claims are anticipated by Kato et al.

8. Claims 1-4, 6-7, and 9-10are rejected under 35 U.S.C. 102(b) as being anticipated by Henry et al., Bioorganic & Medicinal Chemistry Letters, Vol. 8, 1998, pages 3335-3340. Henry et al. disclosed the instant claimed compounds

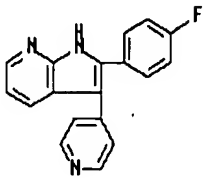
CN 1H-Pyrrolo[2,3-b]pyridine, 4-butoxy-2-(4-fluorophenyl)-6-methoxy-3-(4-pyridinyl)



CN 1H-Pyrrolo[2,3-b]pyridine, 2-(4-fluorophenyl)-6-methoxy-3-(4-pyridinyl)-



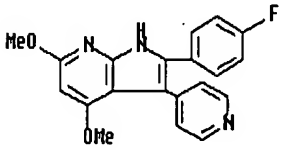
CN 1H-Pyrrolo[2,3-b]pyridine, 2-(4-fluorophenyl)-3-(4-pyridinyl)-



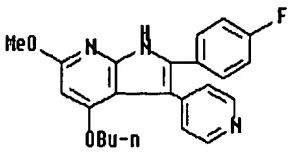
and compositions to treat inflammatory diseases such as rheumatoid arthritis, inflammatory bowl disease, and psoriasis. Therefore, the instant claims are anticipated by Henry et al.

9. Claims 1-4, 6-7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Dodd et al. WO 9847899. Dodd et al. disclosed the instant claimed compounds

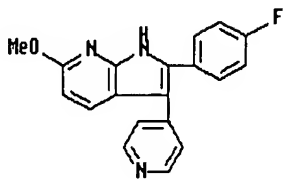
CN 1H-Pyrrolo[2,3-b]pyridine, 2-(4-fluorophenyl)-4,6-dimethoxy-3-(4-pyridinyl)-



CN 1H-Pyrrolo[2,3-b]pyridine, 4-butoxy-2-(4-fluorophenyl)-6-methoxy-3-(4-pyridinyl)-



CN 1H-Pyrrolo[2,3-b]pyridine, 2-(4-fluorophenyl)-6-methoxy-3-(4-pyridinyl)-

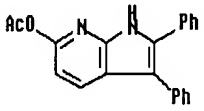


, and

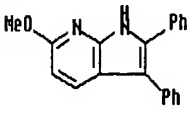
compositions to inhibit the production of a number of inflammatory cytokines to treat diseases associated with overproduction of inflammatory cytokines. Therefore, the instant claim is anticipated by Dodd et al.

10. Claims 1-4, 6-7, and 9-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Herbert et al., Journal of the chemical society [section] C: organic, 1969, Vol. 11, pages 1505-14. Herbert et al. disclosed the instant claimed compounds

CN 1H-Pyrrolo[2,3-b]pyridin-6-ol, 2,3-diphenyl-, acetate (ester)



CN 1H-Pyrrolo[2,3-b]pyridine, 6-methoxy-2,3-diphenyl-



, and compositions with the same activity as the instant claims. Therefore, the instant claim is anticipated by Herbert et al.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Niloofar Rahmani whose telephone number is 571-272-4329. The examiner can normally be reached on Monday through Friday from 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thomas Mckenzie, can be reached on 571-272-0694. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

NILOOFAR RAHMANI
12/19/2006
NR

D.MARGARET SEAMAN
PRIMARY EXAMINER
GROUP 1625